

REMARKS/ARGUMENTS

Claims 1-19 remain pending in this application. Claim 2 has been amended so as to be placed in independent form. Please charge \$200.00 for the additional independent claim to Deposit Account No. 19-4409.

I. Objection to the Claim

In response to the objection to claim 2, claim 2 has been placed in independent form by incorporating the limitations of claim 1 into claim 2. Accordingly, the objection to claim 2 as being in improper dependent form is moot and should be withdrawn.

II. § 103 Rejection

Applicant submits that claims 1-19 are not obvious over U.S. Patent No. 5,290,775 to Sawyer et al. (Sawyer '775) in view of U.S. Patent No. 5,720,951 to Baker (Baker), U.S. Patent Application Publication No. 2003/0064099 to Oshlack et al. (Oshlack), U.S. Patent No. 4,005,038 to Minkoff (Minkoff), U.S. Patent No. 5,962,963 to Komer (Komer), and U.S. Patent No. 5,281,611 to Sawyer et al. (Sawyer '611).

No Prima Facie Case of Obviousness Has Been Established

As the standard for assessing obviousness, MPEP 706.02(j) lists three requirements for establishing a *prima facie* case of obviousness under 35 U.S.C. § 103:

- (1) First, there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the references to arrive at the claimed invention.
- (2) Second, there must be a reasonable expectation of success.
- (3) Finally, the prior art references must teach or suggest all of the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on Applicant's disclosure.

It is respectfully submitted that these three requirements have not been met. Therefore, Applicant respectfully submits that a *prima facie* case of obviousness for rejecting the pending claims has not been established. Claims 1-19 are not anticipated or made obvious by Sawyer '775 in view of Baker, Oshlack, Minkoff, Komer and Sawyer '611.

While Baker, Oshlack and Minkoff disclose the addition of a taste aversive substance to their particular formulations, these references alone or in combination do not suggest the addition of a taste aversive agent into a euthanasia formulation, as claimed by Applicant. See paragraphs 5-15 of the Declaration of Jack I. Shugart attached hereto as Exhibit A (hereinafter "Shugart Declaration"). There is no suggestion or motivation from the cited references, as required for the making of a *prima facie* case of obviousness, to incorporate the taste aversive substance from Baker, Oshlack, or Minkoff into a euthanasia formulation, such as the euthanasia solution of Sawyer '775, Komer or Sawyer '611.

More specifically, there is no suggestion or motivation from the cited references that a taste aversive agent would be chemically compatible and chemically stable with the chemicals in an injectable euthanasia solution. See Shugart Declaration, paragraphs 5 and 6. One of ordinary skill in the art would have concerns that a mixture containing a euthanasia formulation and a taste aversive agent that remained in a jar or vial for an extended period of time would separate thus not allowing a correct dosage of an euthanasia formulation to be measured. See Shugart Declaration, paragraph 7.

In addition, one of ordinary skill in the art would be concerned that the taste aversive agent would interfere with the euthanasia formulation so as to diminish the effectiveness of the

formulation and/or would interfere with the lidocaine in the euthanasia formulation so as to deactivate it causing further pain to the animal being euthanized. See Shugart Declaration, paragraphs 8 and 9. Even the FDA was concerned that the addition of a taste aversive agent would cause additional pain to the animal being euthanized. See Shugart Declaration, paragraph 10.

The only cited reference that discloses or suggests using a taste aversive agent in a pharmaceutical setting is Oshlack, which teaches adding a taste aversive agent to an opioid analgesic. However, the chemical formulation of an opioid analgesic is quite different from the chemical formulation of a euthanasia formulation. Just because a taste aversive agent is chemically compatible and chemically stable with an opioid analgesic does not imply or suggest to one of ordinary skill in the art that a taste aversive agent would be chemically compatible and chemically stable with a euthanasia formulation. See Shugart Declaration, paragraph 13.

With no teaching or suggestion from the cited references to incorporate a taste aversive agent into an injectable euthanasia composition, one of ordinary skill in the art would not find such an addition obvious in view of the fact that numerous chemicals are not compatible with euthanasia formulations. See Shugart Declaration, paragraph 14. For instance, as taught by Sawyer '775 in column 19, lines 40-50, using isopropyl alcohol in an euthanasia formulation provided undesirable effects. Accordingly, there is no reasonable expectation that a person of ordinary skill in the art relying on the cited references would think that a taste aversive agent could be successfully incorporated into a euthanasia formulation. See Shugart Declaration, paragraph 14.

It is important to note that the references cited for disclosing use of a taste aversive agent, Baker, Minkoff, and Oshlack, do not disclose or suggest incorporating a taste aversive agent into

a formulation that is intended for injection, whereas Applicant's claimed composition is an injectable euthanasia composition. There is no disclosure or suggestion by the cited references that a taste aversive agent would be compatible with a formula intended for injection. See Shugart Declaration, paragraph 12. In fact, Oshlack teaches away from an injectable formulation by teaching at paragraph 41 that "[t]he aversive agents of the present invention are preferably used in connection with oral dosage forms...." In fact, Oshlack's only mention of injection involves trying to prevent it.

Paragraph 21 of Oshlack, which is pointed out in the Office Action, does not change the context of paragraph 41. Paragraph 21 merely states that a taste aversive agent is used in Oshlack's analgesic formulation to discourage an abuser from inhaling or swallowing it. Paragraph 21 does not even mention injection, even with respect to an abusive way to use the formulation. Further, there is no disclosure or suggestion by the cited references of how a taste aversive agent would affect an animal's skin and veins when injected therewith. See Shugart Declaration, paragraph 12.

It is important to delicately balance the chemicals in the euthanasia formulation so as not to cause a inhumane death, such as a prolonged death or unwanted side effects during the euthanasia process. Accordingly, one of ordinary skill in the art would not assume that a taste aversive agent could be added to a euthanasia formulation and that an effective injectable euthanasia composition would be created. See Shugart Declaration, paragraph 15.

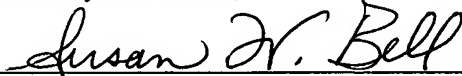
For the foregoing reasons, Applicant submits that claims 1-19 are not anticipated or made obvious by Sawyer '775, in view of Baker, Oshlack, Minkoff, Komer, and Sawyer '611.

III. Conclusion

In view of the foregoing remarks, it is respectfully submitted that the claims are in condition for allowance and eventual issuance. Such action is respectfully requested. Should the Examiner have any further questions or comments which need be addressed in order to obtain allowance, please contact the undersigned attorney at the number listed below.

Acknowledgement of receipt is respectfully requested.

Respectfully submitted,

By: 

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